

### **Remarks**

Before entrance of the present Amendment, claims 1-31 and 112 were pending in the present application and currently stand rejected by the Examiner.

Claims 2 and 5 have been amended in this Response, and no new claims have been added. Specifically, typographical errors have been corrected in claims 2 and 5 as requested by the Examiner. Applicant submits that no new matter is added to the application by the present Amendment.

Applicant respectfully requests reexamination and reconsideration of the case based on the amended claims. Each of the rejections levied in the Office Action is addressed individually below.

**I. Claim Objections.** Claims 2 and 5 have been objected to by the Examiner for various informalities including the misspelling of the words “carbonate” and “diisocyanate”. These typographical errors have been corrected by the present Amendment rendering the Examiner’s objections moot.

**II. Rejection under 35 U.S.C. § 112, second paragraph.** Claim 2 has been rejected by the Examiner under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The Examiner maintains that there is insufficient antecedent basis for the reinforcement because claim 1 is drawn to bone or bone substitutes. In particular, the Examiner maintains that all the materials listed in claim 2 are bone substitutes. However, this is not the case. Claim 2 lists demineralized bone and mineralized bone, which are derived from bone, and would not be considered by one of skill in the art to be bone substitutes but rather bone itself. In fact, the term “bone substitutes” as used in orthopedics refers to any material other than bone. Applicant respectfully submits that it would be incorrect to amend claim 2 to recite only bone substitute materials with bone-derived materials in the list. Furthermore, Applicant has drafted claim 2 to include combinations such as, for example, mineralized bone and calcium carbonate, that is, bone in combination with a bone substitute. There would be no other way to draft claim 2 and

encompass such combinations of bone and bone substitute materials. Applicant, therefore, submits that claim 2 is definite and clear as written and requests that this rejection be removed.

**III. Rejection under 35 U.S.C. § 103(a).** Claims 1-31 and 112 have been rejected by the Examiner under § 103 as being unpatentable over Posnansky *et al.*, U.S. Patent 2,882,249; Boyce *et al.*, U.S. Patent 6,123,731; and Gunatillake *et al.*, *European Cells and Materials* 5:1-16, 2003. The Examiner states the Posnansky *et al.* teaches polyurethanes prepared by reacting hydroxy-containing fatty acids with organic polyisocyanates. More correctly, Posnansky *et al.* teaches the reaction of *non-linear* polyacidesters, not hydroxy-containing fatty acids, with polyisocyanates to form plastic materials. Reaction of the non-linear polyacid polymers with a polyisocyanate leads to the formation of urethane linkages between the polymers. In short, the polyisocyanate crosslinks the polymers to form “even larger molecules.” Col. 1, lines 56-64; col. 2, lines 33-35. The non-linear polyacidester starting material is prepared from a hydroxy-containing monobasic organic acid. Therefore, the molecule reacted with the polyisocyanate is not a biomolecule (*e.g.*, a fatty acid) as claimed in the present invention but a derivative of a biomolecule. Posnansky *et al.* does not in fact teach or suggest reaction of a biomolecule *per se* with a polyisocyanate to form a polyurethane as the Examiner has suggested.

Furthermore, as the Examiner admits Posnansky *et al.* does not teach a reinforcement embedded in the matrix as claimed in the present Application. The Examiner cites Boyce *et al.* for teaching the use of bone combined with a polymer in osteoimplants. However, Applicant respectfully disagrees that Boyce *et al.* provides a teaching of a polyurethane prepared by reacting a biomolecule with a polyisocyanate. Boyce *et al.* teaches an osteoimplant with chemical linkages between the surface-exposed collagen of adjacent partially demineralized bone elements with a nonbioasorbable material. Boyce *et al.* does not teach a polyurethane made from a biomolecule as claimed but rather discloses polyurethanes generally in a long list of possible polymers. The generic disclosure cited by the Examiner in column 4 certainly does not provide a teaching for the use of a polyurethane made from a biomolecule.

Gunatillake *et al.* also does not teach the use of a polyurethane made from a biomolecule as claimed. Gunatillake *et al.* teaches the use of polyurethanes in tissue engineering but does not

disclose the use of biomolecules as the hydroxyl-containing component of the polyurethane. Gunatillake *et al.* is nothing more than an article that reviews the many different biodegradable synthetic polymers for use in tissue engineering. Among these polymers is listed polyurethanes. But nowhere does Gunatillake *et al.* mention the use of “an optionally hydroxylated biomolecule” to form a biodegradable polyurethane polymer. In fact, Gunatillake *et al.* does not mention the use of a biomolecule that has been hydroxylated or a biomolecule that already has a sufficient number of hydroxyl groups to form a polyurethane. There is simply nothing in Posnansky *et al.*, Boyce *et al.*, or Gunatillake *et al.* that teaches the use of a polyurethane made from a biomolecule in a composite as claimed.

As has been pointed out previously, the cited references, even when combined, fail to teach or suggest the use of a biomolecule in the preparation of a polyurethane used in the claimed invention. Therefore, the Examiner has not established a *prima facie* case of obviousness.

Furthermore, the Examiner has provided no teaching of the use of the particular biomolecules listed in claim 6 in preparing a polyurethane for use in a composite nor has the Examiner pointed to a teaching of the use of lecithin as the biomolecule as recited in dependent claim 7. Certainly, the Examiner has not established a *prima facie* case of obviousness with respect to these claims since none of the cited references teach these biomolecules as starting materials for preparing a polyurethane. Applicant requests that this rejection be removed.

In view of the forgoing arguments, Applicant respectfully submits that the present case is now in condition for allowance. A Notice to that effect is requested.

Please charge any fees that may be required for the processing of this Response, or credit any overpayments, to our Deposit Account No. 03-1721.

Respectfully submitted,

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